

**PATENT IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

IN RE APPLICATION OF: YUAN, H., *et al.*

SERIAL No.: 10/591,358

FOR: **TRIPOLIDE LACTONE RING  
DERIVATIVES AS IMMUNOMODULATORS  
AND ANTICANCER AGENTS**

EXAMINER: CHANDRAKUMAR, NIZAL S.

ART UNIT: 1625

CONFIRMATION No.: 9546

**STATEMENT OF FACTS UNDER 37 C.F.R. §1.705(b)(2) IN SUPPORT OF  
REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT**

Mail Stop Patent Ext.  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

This statement of facts is being submitted in support of a Request for Recalculation of Patent Term Adjustment (PTA) in the above-referenced patent application, and is timely submitted before payment of the issue fee. Consideration of the remarks presented herein is respectfully requested.

With the Notice of Allowance mailed 14 April 2010, the estimated patent term was 0 days. However, this application was filed as a national phase filing under 35 U.S.C. § 371, and Applicants note that, under 37 C.F.R. § 1.702(b), for a national phase filing, the actual filing date is the date that the national stage commenced under 35 U.S.C. § 371(b) or (f) (*i.e.*, 30-months from the earliest priority date, or when applicant explicitly requests early processing, respectively), rather than under 35 U.S.C. § 371(c) (the date that the executed inventor declaration was filed). Applicants believe the Patent Office has improperly used the 35 U.S.C. § 371(c) date (*i.e.*, 12 August 2008) for the present application in its estimated PTA calculation, while the actual filing date of 14 August 2006 is the actual filing date from which Patent Term Adjustment should be calculated.

Applicants submit that, due to an incorrect PTA calculation under 37 C.F.R. 1.702(b), the correct Patent Term Adjustment should be a credit of at least 822 days, were the patent to issue today.

**1. Statement of facts**

Applicants' calculations for the correct PTA follow. PTA calculation for the 10/591,358 application begins with its filing under 35 U.S.C. § 371(b) on 14 August 2006.

There are two instances of Patent Office delay under 37 C.F.R. §§1.702(a) and 1.702(b) that would lead to an addition of PTA days and one instance of Applicant delay under 37 C.F.R. §1.704 that would lead to a reduction in PTA days.

1. Under 35 U.S.C. §154(b)(1)(A)(i) and 37 C.F.R. §1.702(a)(1), the Office must mail a notification under 35 U.S.C. §132 or a notice of allowance under 35 U.S.C. §151 not later than 14 months after the filing date of the application. Because the filing date of the application was 14 August 2006, an Office Action was due 14 October 2007. However, the first Office Action, a Restriction Requirement was not sent until 29 June 2009. The Office's delay in mailing this first action results in a credit of 623 days PTA, from 15 October 2007 to 29 June 2009.
2. On 22 February 2008, the Office mailed a Notice of Missing Parts. Applicants' response was due on 22 April 2008, but was not filed until 12 August 2008. Thus, Applicants' delay resulted in a debit of 111 days.
3. Under 35 U.S.C. §154(b)(1)(B) and 37 C.F.R. §1.702(b) and 1.703(b), the Office must issue a patent within three years after the date on which the application was filed (*i.e.*, the date national stage commenced under 35 U.S.C. § 371(b) or (f)). Because the filing date of the application was 14 August 2006, the expiry of the 3-year period to issue was 14 August 2009. Thus, Applicants should receive additional days of credit from 15 August 2009 until the date of issuance for this period B day. For example, if the patent were to issue today, the Patent Office delay would result in a credit of at least an additional 310 days PTA.
6. Thus, the total number of days of PTA should be the sum of [(623 days + at least 310 days = at least 933 days of credit due to Office delays) minus 111 days of debited PTA due to Applicant delays = 822 days].

Applicants herein apply for an adjustment of the patent term due to a net delay in examination by the Patent Office, and respectfully request reconsideration and a recalculation of the Patent Term Adjustment indicated on the Notice of Allowance, mailed 14 April 2010.

**2. Payment of fee under §1.18(e)**

The required fee under 37 C.F.R. §1.18(e) accompanies this statement of facts in support of this application, and Applicants hereby authorizes the Patent Office to charge any other fees that may be due to Deposit Account 50-4616. Because this request is being filed before the payment of issue fee, it is timely filed.

Respectfully submitted,  
KING & SPALDING LLP

Date: 21 June 2010

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